IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON PHARMACEUTICALS LTD. and ALCON RESEARCH, LTD.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Alcon Pharmaceuticals Ltd. and Alcon Research, Ltd. (collectively "Alcon"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of Aurobindo's filing of Abbreviated New Drug Application ("ANDA") No. 206242 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of VIGAMOX® ophthalmic solution, a drug product containing moxifloxacin hydrochloride, prior to the expiration of various U.S. patents.

PARTIES

2. Plaintiff Alcon Pharmaceuticals Ltd. is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Rule Louis d'Affry 6, Case Postale, 1701 Fribourg, Switzerland.

3. Plaintiff Alcon Research, Ltd. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

4. Upon information and belief, Defendant Aurobindo Pharma Ltd. ("Aurobindo Pharma") is a corporation organized and existing under the laws of India, with a place of business at Water Mark Building, Plot No. 11, Survey No. 9, Kondapur, Hitech City, Hyderabad - 500 084, Andhra Pradesh, India.

5. Upon information and belief, Defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810. Upon information and belief, Aurobindo USA is a wholly-owned subsidiary and alter-ego of Aurobindo Pharma. Aurobindo Pharma and Aurobindo USA are collectively referred to herein as "Aurobindo."

6. Upon information and belief, and consistent with their practice with respect to other generic products, Aurobindo Pharma and Aurobindo USA acted in concert to prepare and submit ANDA No. 206242 to the FDA. Upon information and belief, Aurobindo Pharma and Aurobindo USA actively participated in the preparation of ANDA No. 206242 and both entities submitted ANDA No. 206242 to the FDA. Upon information and belief, Aurobindo USA acted as the agent of Aurobindo Pharma in submitting ANDA No. 206242 to the FDA.

7. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 206242, Aurobindo Pharma and Aurobindo USA will act in concert to distribute and sell the generic product described in ANDA No. 206242 (the "Aurobindo Product") throughout the United States and within Delaware.

JURISDICTION AND VENUE

8. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391 and 1400(b), and 2201 and 2202.

9. Upon information and belief, Aurobindo USA is subject to personal jurisdiction in Delaware because, among others things, it is a corporation organized and existing under the laws of the State of Delaware, has a registered agent in Delaware, and is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer CSR" and "Pharmacy – Wholesale" pursuant to 24 Del. C. § 2540.

10. Upon information and belief, Aurobindo Pharma is subject to personal jurisdiction in Delaware because, among other things, Aurobindo Pharma, itself and through its wholly-owned subsidiary Aurobindo USA, has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Aurobindo Pharma, itself and through its wholly-owned subsidiary Aurobindo USA, manufactures, markets and/or sells generic drugs throughout the United States and within the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. Aurobindo Pharma is subject to jurisdiction in Delaware on the basis of its inducement of and/or contribution to Aurobindo USA's acts of infringement in Delaware. In addition, Aurobindo Pharma is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Aurobindo USA and therefore the activities of Aurobindo USA in this jurisdiction are attributed to Aurobindo Pharma.

11. Upon information and belief, Aurobindo Pharma, in concert with Aurobindo USA, is in the business of manufacturing drug products, which the Aurobindo entities manufacture, distribute, sell, or offer to sell throughout the United States, including in Delaware; derive substantial revenue from services or things used or consumed in Delaware; as part of their ordinary business practice of engaging in U.S. patent litigation, have regularly and routinely litigated ANDA cases without contesting jurisdiction in this District; have, directly or through an agent, filed an ANDA, and/or been actively involved in the preparation and submission of an ANDA, for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in ANDA No. 206242 in the United States, including in Delaware; and, upon receiving FDA approval, they intend to offer to sell and sell the generic product described in ANDA No. 206242 in the United States, including in Delaware.

12. Upon information and belief, Aurobindo Pharma formed Aurobindo USA as its U.S. marketing arm and all of the products Aurobindo USA sells are manufactured by Aurobindo Pharma. Upon information and belief, Aurobindo Pharma continues to closely control and dominate Aurobindo USA, by including Aurobindo Pharma directors, officers, and executives on Aurobindo USA's board of directors; the Chairman of Aurobindo Pharma has routinely appointed those board members to the board of Aurobindo USA; the board of directors for Aurobindo USA has never met, nor voted on a chairman. Upon information and belief, the Chairman of Aurobindo Pharma directs the corporate strategy for Aurobindo USA and makes primary decisions without input from Aurobindo USA with respect to real estate transactions, financial decisions, delegation of manufacturing and other corporate-related responsibilities, including the spinning off of subsidiaries from Aurobindo USA.

13. Aurobindo Pharma has represented to the public that Aurobindo USA and Aurobindo Pharma operate as a single entity. For example, in its Annual Reports, published on its website (www.aurobindo.com), Aurobindo Pharma includes the financials of Aurobindo USA and has in prior years explicitly identified Aurobindo USA as among "companies under the same management."

14. Upon information and belief, Aurobindo Pharma has availed itself of the legal protections of the state of Delaware by filing counterclaims affirmatively seeking relief in other prior actions in this Court, including in *Sanofi-Aventis et al. v. Actavis South Atlantic LLC et al.*, C.A. No. 07-572 (D. Del.); *Helsinn Healthcare SA et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 13- 688 (D. Del.); and *UCB Inc. et al. v. Aurobindo Pharma Ltd., et al.*, C.A. No. 13-1210 (D. Del.). Aurobindo Pharma has also not contested jurisdiction in prior litigation in this District, including in *Helsinn Healthcare SA v. Aurobindo Pharma Ltd. et al.*, C.A. No. 13-688 (D. Del.), and *UCB Inc., et al. v. Aurobindo Pharma Ltd., et al.*, C.A. No. 13-1210 (D. Del.).

COUNT I – INFRINGEMENT OF THE '830 PATENT

15. Alcon incorporates each of the preceding paragraphs 1-14 as if fully set forth herein.

16. United States Patent No. 6,716,830 ("the '830 patent"), titled "Ophthalmic Antibiotic Compositions Containing Moxifloxacin" (Exhibit A hereto), was duly and legally issued on April 6, 2004 to Alcon, Inc., as assignee of Gerald Cagle, Robert L. Abshire, David W. Stroman, and John M. Yanni.

17. Alcon, Inc.'s interest in the '830 patent has been subsequently assigned to Alcon Pharmaceuticals Ltd. Alcon Pharmaceuticals Ltd. owns the '830 patent and will be substantially and irreparably damaged by infringement of the '830 patent.

18. Alcon Research, Ltd. has been granted an exclusive license under the '830 patent. Alcon Research, Ltd. will be substantially and irreparably damaged by infringement of the '830 patent.

19. The '830 patent claims, *inter alia*, topical ophthalmic pharmaceutical compositions comprising moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration of 0.1 to 1.0 wt. % of moxifloxacin and a pharmaceutically acceptable vehicle therefor.

20. The FDA's "Orange Book" lists patents associated with approved drugs. The '830 patent is listed in the "Orange Book" in association with VIGAMOX® ophthalmic solution.

21. By letter dated June 2, 2014 (the "Notice Letter"), Aurobindo notified Alcon that it had submitted ANDA No. 206242 to the FDA. The purpose of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, and sale of an ophthalmic drug product containing moxifloxacin hydrochloride prior to the expiration of, *inter alia*, the '830 patent.

22. In the Notice Letter, Aurobindo also notified Alcon that, as part of its ANDA, Aurobindo had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

23. Aurobindo's submission of ANDA No. 206242 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Aurobindo Product before the expiration of the '830 patent is an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

24. Upon information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Aurobindo Product immediately and imminently upon approval of ANDA No. 206242.

25. The drug product containing moxifloxacin hydrochloride that is the subject of ANDA No. No. 206242 is covered by one or more claims of the '830 patent.

26. The manufacture, use, sale, offer for sale, or importation of the Aurobindo Product would infringe one or more claims of the '830 patent.

27. Upon information and belief, the use of the Aurobindo Product in accordance with and as directed by Aurobindo's proposed product labeling would infringe one or more claims of the '830 patent.

28. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '830 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

29. Upon information and belief, Aurobindo has knowledge of the claims of the '830 patent. Notwithstanding this knowledge, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import the Aurobindo Product with its product labeling following upon FDA approval of ANDA No. 206242 prior to the expiration of the '830 patent.

30. The foregoing actions by Aurobindo constitute and/or will constitute infringement and active inducement of infringement of the '830 patent.

31. Upon information and belief, Aurobindo has acted with full knowledge of the '830 patent and without a reasonable basis for believing that it would not be liable for infringement of the '830 patent and/or active inducement of infringement of the '830 patent.

32. Unless Aurobindo is enjoined from infringing and inducing infringement of the '830 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

COUNT II – INFRINGEMENT OF THE '070 PATENT

33. Alcon incorporates each of the preceding paragraphs 1-32 as if fully set forth herein.

34. United States Patent No. 7,671,070 ("the '070 patent"), titled "Method of Treating Ophthalmic Infections with Moxifloxacin Compositions" (Exhibit B hereto), was duly and legally issued on March 2, 2010 to Alcon, Inc., as assignee of Gerald Cagle, Robert L. Abshire, David W. Stroman, and John M. Yanni.

35. Alcon, Inc.'s interest in the '070 patent has been subsequently assigned to Alcon Pharmaceuticals Ltd. Alcon Pharmaceuticals Ltd. owns the '070 patent and will be substantially and irreparably damaged by infringement of the '070 patent.

36. Alcon Research, Ltd. has been granted an exclusive license under the '070 patent. Alcon Research, Ltd. will be substantially and irreparably damaged by infringement of the '070 patent.

37. The '070 patent claims, *inter alia*, a method of treating ophthalmic infections, which comprises topically applying to the eye a therapeutically effective amount of a pharmaceutical composition comprising moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration of 0.1 to 1.0 wt. % of moxifloxacin and a pharmaceutically acceptable vehicle therefor.

38. The '070 patent is listed in the "Orange Book" in association with VIGAMOX® ophthalmic solution.

39. In the Notice Letter described in paragraph 21 above, Aurobindo notified Alcon that it had submitted ANDA No. 206242, to the FDA. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and sale of the Aurobindo Product prior to the expiration of, *inter alia*, the '070 patent.

40. In the Notice Letter, Aurobindo also notified Alcon that, as part of its ANDA, Aurobindo had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

41. Aurobindo's filing of ANDA No. 206242 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Aurobindo Product before the expiration of the '070 patent is an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

42. Upon information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Aurobindo Product immediately and imminently upon approval of ANDA No. 206242.

43. The approved use of VIGAMOX® is covered by one or more claims of the '070 patent.

44. Upon information and belief, the use of the Aurobindo Product in accordance with and as directed by Aurobindo's proposed product labeling would infringe one or more claims of the '070 patent.

45. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '070 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

46. Upon information and belief, Aurobindo has knowledge of the claims of the '070 patent. Notwithstanding this knowledge, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import the Aurobindo Product with its product labeling following FDA approval of ANDA No. 206242 prior to the expiration of the '070 patent.

47. Upon information and belief, Aurobindo knows that the Aurobindo Product and its product labeling are especially made or adapted for use in infringing the '070 patent, the Aurobindo Product is not a staple article or commodity of commerce, and that the Aurobindo Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '070 patent immediately and imminently upon approval of ANDA No. 206242.

48. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '070 patent, active inducement of infringement of the '070 patent, and contribution to the infringement by others of the '070 patent.

49. Upon information and belief, Aurobindo has acted with full knowledge of the '070 patent and without a reasonable basis for believing that it would not be liable for active inducement of infringement of the '070 patent, and/or contributing to the infringement by others of the '070 patent.

50. Unless Aurobindo is enjoined from infringing, inducing infringement and contributing to the infringement of, the '070 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

COUNT III – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '830 PATENT

51. Alcon incorporates each of the preceding paragraphs 1-50 as if fully set forth herein.

52. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Alcon on the one hand and Aurobindo on the other regarding Aurobindo's infringement of the '830 patent and active inducement of infringement of the '830 patent.

53. The '830 patent claims, *inter alia*, topical ophthalmic pharmaceutical compositions comprising moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration of 0.1 to 1.0 wt. % of moxifloxacin and a pharmaceutically acceptable vehicle therefor.

54. In the Notice Letter described in paragraph 21 above, Aurobindo notified Alcon that Aurobindo had submitted ANDA No. 206242 to the FDA. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and sale of the Aurobindo Product prior to the expiration of, *inter alia*, the '830 patent.

55. In the Notice Letter, Aurobindo also notified Alcon that, as part of its ANDA, Aurobindo had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

56. Upon information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Aurobindo Product immediately and imminently upon approval of ANDA No. 206242.

57. The drug product containing moxifloxacin hydrochloride that is the subject of ANDA No. 206242 is covered by one or more claims of the '830 patent.

58. The manufacture, use, sale, offer for sale, or importation of the Aurobindo Product would infringe one or more claims of the '830 patent.

59. Upon information and belief, the use of the Aurobindo Product in accordance with and as directed by Aurobindo's proposed product labeling would infringe one or more claims of the '830 patent.

60. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '830 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

61. Upon information and belief, Aurobindo has knowledge of the claims of the '830 patent. Notwithstanding this knowledge, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import the Aurobindo Product with its product labeling following upon FDA approval of ANDA No. 206242 prior to the expiration of the '830 patent.

62. The foregoing actions by Aurobindo constitute and/or will constitute infringement and active inducement of infringement of the '830 patent.

63. Upon information and belief, Aurobindo has acted with full knowledge of the '830 patent and without a reasonable basis for believing that it would not be liable for infringement of the '830 patent and/or active inducement of infringement of the '830 patent.

64. Unless Aurobindo is enjoined from infringing and inducing infringement of the '830 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

65. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of the Aurobindo Product, or any other drug product that is covered by United States Patent No. 6,716,830, will infringe and/or induce the infringement of that patent.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '070 PATENT

66. Alcon incorporates each of the preceding paragraphs 1-65 as if fully set forth herein.

67. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Alcon on the one hand and Aurobindo on the other regarding Aurobindo's active inducement of infringement of the '070 patent, and/or contributing to the infringement by others of the '070 patent.

68. The '070 patent claims, *inter alia*, a method of treating ophthalmic infections, which comprises topically applying to the eye a therapeutically effective amount of a pharmaceutical composition comprising moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration of 0.1 to 1.0 wt. % of moxifloxacin and a pharmaceutically acceptable vehicle therefor.

69. In the Notice Letter described in paragraph 21 above, Aurobindo notified Alcon that Aurobindo had submitted ANDA No. 206242, to the FDA. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and sale of the Aurobindo Product prior to the expiration of, *inter alia*, the '070 patent.

70. In the Notice Letter, Aurobindo also notified Alcon that, as part of its ANDA, Aurobindo had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

71. Upon information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Aurobindo Product immediately and imminently upon approval of ANDA No. 206242.

72. The approved use of VIGAMOX® is covered by one or more claims of the '070 patent.

73. Upon information and belief, the use of the Aurobindo Product in accordance with and as directed by Aurobindo's proposed product labeling would infringe one or more claims of the '070 patent.

74. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '070 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

75. Upon information and belief, Aurobindo has knowledge of the claims of the '070 patent. Notwithstanding this knowledge, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import the Aurobindo Product with its product labeling following FDA approval of ANDA No. 206242 prior to the expiration of the '070 patent.

76. Upon information and belief, Aurobindo knows that the Aurobindo Product and its product labeling are especially made or adapted for use in infringing the '070 patent, the Aurobindo Product is not a staple article or commodity of commerce, and that the Aurobindo Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '070 patent immediately and imminently upon approval of ANDA No. 206242.

77. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '070 patent, active inducement of infringement of the '070 patent, and contribution to the infringement by others of the '070 patent.

78. Upon information and belief, Aurobindo has acted with full knowledge of the '070 patent and without a reasonable basis for believing that it would not be liable for active inducement of infringement of the '070 patent, and/or contributing to the infringement by others of the '070 patent.

79. Unless Aurobindo is enjoined from infringing, inducing infringement and contributing to the infringement of, the '070 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

80. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of the Aurobindo Product, or any product whose use is covered by United States Patent No. 7,671,070, will infringe, induce the infringement of, and/or contribute to the infringement by others of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that United States Patent Nos. 6,716,830 and 7,671,070 are valid and enforceable, and have been infringed under 35 U.S.C. § 271(e)(2) by Aurobindo's submission to the FDA of its ANDA No. 206242;

(b) A judgment providing that the effective date of any FDA approval of ANDA No. 206242 for the Aurobindo Product, or any other drug product that infringes or the use of which infringes United States Patent No. 6,716,830 or United States Patent No. 7,671,070, be not earlier than the latest of the expiration dates of those patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction against any infringement, or inducement of infringement, by Aurobindo of United States Patent No. 6,716,830, through the

commercial manufacture, use, sale, offer for sale, or importation into the United States of the Aurobindo Product or any other drug product that is covered by that patent;

(d) A preliminary and permanent injunction against any inducement of infringement, or contribution to infringement, by Aurobindo of United States Patent No. 7,671,070, through the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Aurobindo Product or any other drug product whose use is covered by that patent;

(e) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of the Aurobindo Product, or any other drug product that is covered by United States Patent No. 6,716,830, will infringe and/or induce the infringement of that patent;

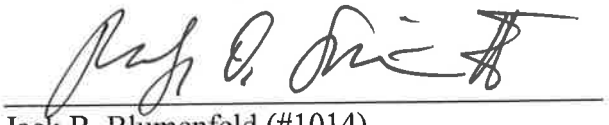
(f) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of the Aurobindo Product, or any product whose use is covered by United States Patent No. 7,671,070, will infringe, induce the infringement of, and/or contribute to the infringement by others of that patent;

(g) A declaration that this in an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(h) Costs and expenses in this action; and

(i) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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